UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION NO. 2:12-md-02327**
	:	**MDL No. 2327**
This Document Applies To All Actions	:	Judge Joseph R. Goodwin

PLAINTIFFS' RESPONSE TO DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO AMEND FIRST AMENDED MASTER LONG FORM COMPLAINT AND JURY DEMAND AND AMENDED MASTER SHORT FORM COMPLAINT

Plaintiffs in the above-styled MDL proceeding respond to Defendants' opposition to Plaintiff's motion to move the Court for leave to amend their First Amended Master Long Form Complaint and Amended Master Short Form Complaint. Additionally, Plaintiffs attach their Third Amended Master Long Form Complaint in order to address the omission of the additional jurisdictional and venue allegations as pointed out by Defendants it its Opposition (Attached hereto as Exhibit 10).

I. ARGUMENT

Defendants only objection to Plaintiffs' motion to amend its master complaint relates to the addition of the "negligent training" count to its master pleading stating that such a claim is "futile" because there is no duty to train physicians and that Plaintiffs' proposed new count merely restates their negligence and failure to warn claims..[1] However, Defendants arguments are flawed.

Plaintiffs pled in their Master complaint that Defendants failed to properly and adequately warn and instruct the Plaintiffs and their health care providers as to the risks and benefits of the Defendants' Pelvic Mesh Products and procedures. Of particular importance is the fact that Defendants not only designed, manufactured and marketed the medical device at issue in this litigation but also went to great lengths to create and market not just a strip of mesh, but a specific procedure with insertion tools they knew would be required in order for surgeons to implant their device. Indeed, Defendants' Prolift and

[1]Defendant's Opposition to Plaintiff's Motion to Amend First Amended Master Long Form Complaint and Jury Demand and Amended Master Short Form Complaint [Doc. 918] at 3.

TVT products are all sold as a "kit" that includes not just the mesh, but the insertion tools and the implantation instructions.

As the discovery in this case has progressed, it has become apparent that the Defendants not only breached their duty to properly warn physicians of the risks associated with their "kits," but Defendants also voluntarily assumed and then breached their duty to train physicians to properly perform the medical procedures for implanting Defendants' Pelvic Mesh Products. Indeed, Defendants' own witnesses have admitted that they assumed such a duty. By assuming this duty, Defendants had an obligation to the Plaintiffs, as purchasers and end-users of the Pelvic Mesh Products, to ensure that Plaintiffs' physicians were adequately trained, educated and/or instructed to determine the appropriateness and efficacy of the products implanted in Plaintiffs during their medical care and treatment. See Plaintiffs' First Amended Master Long Form Complaint and Jury Demand and Amended Master Short Form Complaint.

It is well established that once a defendant voluntarily undertakes a duty that it must carry out that duty with reasonable care. The common law recognizes that an actor, by his affirmative acts, can create or assume a duty where none otherwise would have existed. *Restatement (Second) of Torts §§ 321-324A* (1965). This premise has also been extended to medical device cases. Although a manufacturer may not automatically have a duty to properly train, instruct, or assist a physician on the surgical implantation and use of its device, the manufacturer "can affirmatively undertake that duty." *See Lemon v. Anonymous Physician*, 2005 WL 2218359, at *2 (S.D. Ind. Sept. 12, 2005) citing to *Lucas v. Dorsey Corp*., 609 N.E.2d 1191, 1200-1201 (Ind. Ct. App. 1993) (A duty of care arises when a party voluntarily or gratuitously assumes such a duty) citing to *Phillips v. United Engineers* (1986), Ind. App., 500 N.E.2d 1265, 1269 citing to *Clyde E. Williams and Associates, Inc. v. Boatman*, (1978) 176 Ind. App. 430, 375 N.E.2d 1138, trans. denied; *Perry v. Northern Indiana Public Service*, 433 N.E.2d 44; *Plan-Tec, Inc., (1983) Ind. App*., 443 N.E.2d 1212. The assumption of a duty creates a special relationship between the parties and a corresponding duty to act in the manner of a reasonably prudent person. *Clyde E. Williams*, 176 Ind. App. 430, 375 N.E.2d 1138; Plan-Tec, 443 N.E., 2d 1212. Failure to act in a reasonable manner will give rise to an action for negligence. Id. Whether a party has assumed a duty and the extent of that

duty, if any, are questions for the trier of fact. *Perry*, 433 N.E.2d at 50. Other states also formally address the doctrine of a defendant's "voluntary duty." *See Banfield v. Addington*, 140 So. 893 (Fla. 1932); *LM v. United States*, 344 F.3d 695 (7th Cir. 2003); and *Torrington Co. v. Stutzman*, 46 S.W.3d 829 (Tex. 2000).

This Court has already recognized the concept of negligent training in In Re: C.R. Bard, Inc., Pelvic Repair System Product Liability Litigation, MDL 2187, *Jones v. C.R. Bard, Inc.*, Case No. 2:11-cv-114. As your honor is aware, the Court entered an Order granting partial summary judgment in favor of Bard on the issue of "whether the inadequate warning proximately caused the alleged injury" in part because the doctor never read the IFU. (Mem. Op. and Ord. [Docket 299], at 2). Plaintiffs requested reconsideration under Federal Rule of Civil Procedure 54(b) arguing that the Court overlooked causation evidence in the record, including but not limited to, disclosures made by Bard to Plaintiff's implanting physician during a 2-day Bard training program which included a didactic seminar, live speakers, and physician training in a cadaver lab. (Mot. to Amend Interlocutory Order [Docket 292] at 2). In addition, the implanting physician also testified that he received: direct training from Bard regarding the Avaulta product, DVDs from Bard, brochures relating to the Avaulta products, and was accompanied by a Bard sales representative in the operating room "almost every time that I can remember." (Mot. to Amend Interlocutory Order [Docket 292] at 6-7 attached hereto as Exhibit 2). However, plaintiffs' request for reconsideration was denied and the Court would not rule on the plaintiff's argument regarding a claim of negligent training since such a claim was never brought in the Master or Short-Form Complaint.[2] Following the insight provided by the Court, and consistent with the discovery developed in this case regarding the woefulness of Defendants training,[3] Plaintiffs in the instant case have requested leave of this Court to amend their Master and Short-form complaints to add the claim of negligent training.

[2] "To the extent that the plaintiff may be arguing a claim of negligent training here, such a claim was never brought in the Master or Short-Form Complaint, and I will therefore only analyze the plaintiff's argument in the context of her failure to warn claim." Mem. Op. and Ord. [Docket 299] at n1 – Ex. 1.

[3] For example, Ethicon's own documents reveal that due to lack of funding of its professional education programs, for the TVT products, Ethicon's sales reps (who are not physicians at all) were instructed to tell the physicians to

Plaintiffs argue that failure to warn should include not only the substance of the warning, but the conveyance of the warning – making sure the doctor reads it. Although, generally, "[w]here warning is given, *the seller may reasonably assume that it will be read and heeded*," *In re Levaquin Products Liability Litigation*, 700 F.3d 1161, C.A.8 (Minn.) *citing to J & W Enters., Inc. v. Economy Sales, Inc.*, 486 N.W.2d 179, 181 (Minn.Ct.App.1992)(emphasis in *J & W Enters., Inc.*) (quoting *Restatement (Second) of Torts* § 402A, cmt. j (1965)) (internal quotation marks omitted), failure to read a warning does not necessarily bar recovery where, as here, the plaintiff claims inadequate communication of the warning caused the failure to read it. *Cf. Johnson v. Niagara Mach. & Tool Works*, 666 F.2d 1223, 1225–26 & n. 3 (8th Cir.1981) (On a failure to warn claim, affirming the district court's grant of a directed verdict for the defendant because the plaintiff had not read the warning, and leaving open the possibility of a different result if the plaintiff had claimed the warning's form was inadequate). To prove causation in a failure to warn case, it is sufficient to present testimony that purchasers would have avoided the risk of harm had they been told of the relevant danger. *See Erickson*, 455 N.W.2d at 78. Because the learned intermediary doctrine applies, defendant had a duty to warn the plaintiff's treating physician rather than the plaintiff directly. *See Mulder*, 181 N.W.2d at 885 & n. 1, and the principle of *Erickson* should apply with equal force in the learned intermediary doctrine context.

To support their proposition that there is no independent duty to provide training to physicians, Defendants attempt to rely on the learned intermediary doctrine as it has been applied when a product is sold to a "sophisticated professional." (Defendant's Opp. [Doc. 918] at 3-5). However, this argument is without merit. Moreover, the analogies used by Defendants not only sound "preposterous," as Defendants suggest, they are indeed "preposterous" in light of the fact that Defendants themselves created a duty separate from the duty to warn when they voluntarily undertook the duty to train and certify physicians and then breached that duty. That very significant fact by itself distinguishes this case from the cases cited by defendants for this proposition. This Court should not allow Defendants to expand the

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forego cadaver labs and other more costly training and simply train the doctors themselves using a 45 minute DVD. Ex. 3 - Parisi depo testimony 6/6/13 Page 479:6 – 497:17; Ex. 4 - ETH.MESH.05795322

learned intermediary doctrine to immunize manufacturers when they voluntarily engage in the negligent training of physicians. Especially as in this case when the true purpose for the Defendants' professional education program is for monetary gain. Defendants, through the use of Key Opinion Leaders ("KOL"), preceptors, proctors, sales representatives and other agents, voluntarily and actively sought to "train" other physicians on its Pelvic Mesh products in an effort to get them to adopt the use of their products and increase sales.[4] KOLs were also involved in the marketing of Defendant's Pelvic Mesh products.[5] After the 2008 FDA alert, Prof Ed sent out its KOLs, who acted like Ethicon sales reps to help protect the TVT market share.[6][7]

Defendants' attempt to distract this Court by also suggesting that Plaintiffs' claims are somehow preempted by the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301. (Defendant's Opp. [Doc. 918] at 5). Class II devices, such as Defendants' pelvic mesh devices, are subject to a limited form of review to market a new device requiring the manufacturer to merely submit a "premarket notification" to the FDA (the process is known as a "§ 510(k) process," after the number of the section in the original Act).[8] Devices that are "substantially equivalent" to a preexisting medical device are exempt from the PMA process and instead subject to a streamlined approval process.[9] "State . . . requirements are preempted only when . . . there are . . . specific [federal] requirements applicable to a particular device . . . thereby making any existing divergent State . . . requirements applicable to the device different from, or in addition to, the specific [federal] requirements." 21 CFR § 808.1(d) (1995) (emphasis added).[10] To the

[4] EX3. - Parisi depo testimony 6/6/13 Page 418:21 – 421:12; Ex. 5 - ETH.MESH.00235558; Ex. 3 - Parisi depo testimony 6/6/13 Page 510:8-511:2; Ex. 6 - Pattyson depo testimony 7/11/13 Page 424:21 – 426:24

[5] Ex. 7 - ETH.MESH.00029667

[6] Ex. 6 - Pattyson depo testimony 7/11/12 Pages 336:2 – 345:9; Ex. 8 - ETH.MESH.01706065

[7] "I (KOL Dr. Doug Grier) use TVT which has been studied more than any sling so it's clear what risks exists." An Ethicon KOL only needs to work 33 days to make $100K! ; Ex. 9 - ETH.MESH.07386591.

[8] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-479 (U.S. 1996) and its progeny.

[9] *Id.* citing *21 U.S.C.S. § 360e(b)(1)(B)*.

[10] *Id.* at 506.

extent Defendants argue that the assumption of a duty is preempted, such is not the law under this section of the original act.

Finally, Defendants claim that Plaintiffs' proposed new count is merely a restatement of their negligence and failure to warn claims. However, as discussed in more detail above, Defendants assumed an obligation, guaranteed, promised, and accepted the responsibility to train physicians through their Physician Education Programs prior to the physician receiving certification to perform its complex and dangerous procedure, all in an effort to get physicians to adopt their products and increase sales.[11]

Plaintiffs' proposed Second Amended Master Long Form Complaint and Amended Master Short Form Complaint properly sets forth allegations that Defendants voluntarily undertook a duty to train implanting physicians regarding the complexities of implanting their pelvic mesh products. Based on these facts, Plaintiffs' Motion to Amend is not futile and should be granted. *See Rollins v. St. Jude Med.*, 583 F. Supp. 2d 790, 802 (W.D. La. 2008) (granting ten (10) days for Plaintiff to amend her complaint to add a failure to train claim.)

More importantly, as discussed above, this Court has acknowledged a difference between failure to warn and failure to train that cannot be overcome absent proper pleading in Plaintiffs' Master and Short-Form Complaints. Therefore, Plaintiffs respectfully request leave to amend their pleadings to include a claim for Negligent Training.

IV. CONCLUSION

As set forth more fully in Plaintiffs' Motion for Leave to File the Second Amended Master Long Form Complaint and Jury Demand and Second Amended Short Form Complaint, Plaintiffs have demonstrated that their request for leave to amend is not accompanied by prejudice, delay, or bad faith. Thus, Plaintiffs' renew their request that the Court grant Plaintiffs' Motion for Leave to File the Third Amended Master Long Form Complaint and Jury Demand and Second Amended Short Form Complaint.

[11] Ex. 3 - Parisi depo testimony 6/6/13 Page 418:21 – 421:12; Ex. 5 - ETH.MESH.00235558; Ex. 3 - Parisi depo testimony 6/6/13 Page 510:8-511:2; Ex. 6 - Pattyson depo testimony 7/11/13 Page 424:21 – 426:24

Dated: November 21, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 21, 2013, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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